From: OC GCP Questions
To: [redacted]
Subject: Five Day reports of Emergency Use of a Test Article
Date: Tuesday, June 24, 2014 10:42:32 AM
Attachments: Emergency use question.PDF

Good morning –

In addition to the information below, please see an extensive emergency use email that was written in 2012 (attached above). The information in the attachment might be helpful to you.
The investigator should follow the plan as outlined in the report made to the IRB within 5 working days after the use of the test article, and monitor the patient outcomes. If there is any change in that plan, then the investigator should submit changes to the IRB in accordance with 21 CFR 312.66.

The IRB should confirm whether the conditions for emergency use were met and review the informed consent form, or if the conditions outlined in 21 CFR 50.23 were met, that the information was appropriately documented. The regulations allow the IRB flexibility regarding how to handle review of the 5 day report of an emergency use. If there are any subsequent changes in the plan submitted to the IRB, then the IRB should follow their written procedures for review.

If you feel that the IRB is not operating in full compliance with FDA regulations, you may report them to the specific FDA Center. Please note the Centers are specific to the test article (drug, biologic, or device)

Reporting Complaints Related to FDA-Regulated Clinical Trials

Biologics studies (including gene therapy and vaccine studies):
Call 301-827-6221
Fax 301-827-6748
Email OCOD@fda.hhs.gov
(Division of Communication and Consumer Affairs, CBER)

Drug studies:
Call 301-796-3150
Fax 301-847-8748
Email CDER-OSI@fda.hhs.gov
(Division of Scientific Investigations, Office of Compliance, CDER)

Medical Device studies:
Call 301-796-5490
Fax 301-847-8136
Email bimo@cdrh.fda.gov
(Division of Bioresearch Monitoring, Office of Compliance, CDRH)

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

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: [redacted]
Sent: Monday, June 23, 2014 1:55 PM
To: OC GCP Questions
Cc: [Redacted]
Subject: Five Day reports of Emergency Use of a Test Article

Dear OGCP Staff,

Regarding the emergency use of a test article, FDA requires a report sent by the investigator within five days to the IRB. What are the investigators responsibilities/options when the IRB is an independent IRB and the policy of the independent IRB is not to accept for review emergency use of a drug, biologic or device?

[Redacted]