From: OC GCP Questions
To: [redacted]
Subject: should this be reported?
Date: Monday, August 20, 2018 8:26:00 AM
Attachments: [redacted]

Good morning –

There is not enough information in your email for me to comment on whether the incident should be reported.

Generally, it is the sponsor's responsibility to report serious and unexpected AE's to FDA. (Of course, where you have a sponsor/investigator at the institution, the sponsor/investigator is responsible). I would still maintain that safety reporting to FDA and OHRP where appropriate is a sponsor responsibility.

Again, the sponsor would normally report an expected serious adverse event as an expedited IND safety report to FDA. Expected serious adverse events would only be reported as expedited IND safety reports if they represent an increased rate of occurrence of serious suspected adverse reaction (21 CFR 312.32(c)(1)(iv)).

> *(c)(1) IND safety reports. The sponsor must notify FDA and all participating investigators (i.e., all investigators to whom the sponsor is providing drug under its INDs or under any investigator's IND) in an IND safety report of potential serious risks, from clinical trials or any other source, as soon as possible, but in no case later than 15 calendar days after the sponsor determines that the information qualifies for reporting under paragraph (c)(1)(i), (c)(1)(ii), (c)(1)(iii), or (c)(1)(iv) of this section. In each IND safety report, the sponsor must identify all IND safety reports previously submitted to FDA concerning a similar suspected adverse reaction, and must analyze the significance of the suspected adverse reaction in light of previous, similar reports or any other relevant information.*

Please see FDA's guidance "Safety Reporting Requirements for INDs and BA/BE Studies" (available at www.fda.gov/downloads/Drugs/.../Guidances/UCM227351.pdf). This guidance was issued in concert with FDA's final rule, which published on September 29, 2010, "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products." Information on this final rule is available at the following link: www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm.

If I have not specifically answered your question, you may send your email to the Center for Drugs (CDER) Office of Medical Policy (OMP) as they are the experts on safety reporting and wrote the final rule and guidance on safety reporting (CDEROMP@fda.hhs.gov)

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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: Friday, August 17, 2018 1:04 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: should this be reported?

Good morning,
We had an incident in a research study involving a lawfully marketed drug [redacted]

The incident locally did not involve any adverse event to the participant, but involved study personnel and the tasks they were performing related to the administration of the study medication. The IRB identified the incident as a serious, related and unexpected event r/t this study. The study was also put on hold for a brief time by the IO to address the personnel issues and assure patient safety was not affected.

Is reporting required for this incident?
Thank you.

[redacted]