From: OC GCP Questions
To: [redacted]
Subject: Question about adverse event reporting
Date: Wednesday, May 20, 2015 12:37:48 PM

Good afternoon –

I believe that if a study is exempt from the IDE requirements the study is also exempt from the IDE safety reporting requirements. However it might be best to send your question to the Center for Devices (CDRH) at DICE@fda.hhs.gov. You can also contact the Office of InVitro Diagnostics. Please see their web link below a few links to guidance documents.

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf

Investigational Device Exemption (IDE) > IDE Approval Process

CDRH Offices > Office of In Vitro Diagnostics and Radiological Health

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

From: [redacted]
Sent: Tuesday, May 19, 2015 5:06 PM
To: OC GCP Questions
Subject: Question about adverse event reporting

Hello,
I have a question about when adverse event reporting is needed for a study of an in vitro diagnostic device that is IDE exempt. The study collects sample leftover from a standard of care procedure (an additional procedure for the study does not occur, but additional sample might be taken for the study alone). The samples are frozen and later tested on the device, and the results are not provided back for treatment.

The subjects enrolling in the study are typically ill patients and thus may experience a range of outcomes during their hospital procedure/stay, including death. As there is no study procedure done to the patient solely as part of the study, is the PI required to review these outcomes as potential adverse events and report them to the IRB? Does it make a difference if no additional sample was taken vs additional sample taken?

I can provide more detail if that would be helpful.

Thank you,

[redacted]