From: OC GCP Questions
To: [redacted]
Subject: IATA Training Documentation
Date: Wednesday, August 13, 2014 11:22:09 AM

Good morning [redacted] –

There is no FDA requirement that study staff have IATA training. However, it would be up to the sponsor to determine if they would like staff to have this type of training.

The expectation is that investigators, sub-investigators, and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required training, in which case the investigator and sub-investigators would be expected to meet that training requirement in order to comply with the sponsors requirements.

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: Wednesday, August 13, 2014 9:26 AM
To: OC GCP Questions
Subject: IATA Training Documentation

Hi,

Would the FDA expect to see documentation that study site personnel have international Air Transport Association (IATA) training if the study requires the shipment of blood and tissue samples?

I don't believe I've ever seen that requirement, but I have run into some who feel that having that training and documentation is required.

Thanks for your input,
[redacted]