From: OC GCP Questions
To: [redacted]
Subject: Question regarding Blood storage.
Date: Wednesday, September 19, 2018 8:24:00 AM
Attachments: [redacted]
Importance: High

Good morning –

We can only speak to temperature storage of an investigational product for a FDA-regulated study. It best to contact your institutional blood bank for guidance on blood storage temperatures.

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, September 17, 2018 3:52 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question regarding Blood storage.
Importance: High

Hello,
We are opening a mammography trial in an outpatient clinic setting where blood (optional) will be drawn, spun, aliquoted & frozen for batch shipment every month. Do we need to monitor the temperature since this is not a lab setting.

Please provide guidance or any regulations pertaining to this type of situation.

Thank you.
[redacted]

[redacted]