From: OC GCP Questions
To: [redacted]
Subject: Provenance Testing for Specimen Validity
Date: Thursday, February 01, 2018 9:19:00 AM
Attachments: [redacted]

Good morning –

Based on the limited information in your email, I don't believe that the subject would need to be reconsented as long as the original consent outlines the first blood draws. However, you would have to ask yourself what valves you will use for the clinical study if the second genetic testing labs are different than the original values. If you are still unclear, I suggest asking your reviewing IRB and/or the sponsor of the study.

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: Wednesday, January 31, 2018 4:29 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Provenance Testing for Specimen Validity

Good Afternoon,

If a patient's lab results show anomalous values which do not match the normal trends for that patient over time, can a laboratory genetically test (provenance test) the samples it has in retain to verify they are those of the same individual without obtaining additional consent from the patient?

Thank you

[redacted]