From: OC GCP Questions
To: [redacted]
Subject: Using subjects blood samples for further analysis after the study closure
Date: Thursday, September 07, 2017 11:29:00 AM
Attachments: [redacted]

Good morning --

From an FDA perspective in general, if the subject's specimens are identifiable, but the subject has given consent (and has not rescinded it), the samples could be used. If the subject's specimens are identifiable, but the subject withdraws consent for future testing on those specimens, then such specimens should not be used.

If, however, the specimens have been de-identified, the specimens could continue to be used for research purposes, per the policy outlined in FDA's "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable." https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071265.pdf For example, if the specimens are left-over specimens from routine clinical procedures and no information about the individuals is either known upon collection or retained with the specimens, it is doubtful informed consent is needed. On the other hand, if the samples are collected prospectively, informed consent from individuals "donating" the specimens would be needed. FDA is using enforcement discretion with regard to the need for informed consent for studies that use left-over samples without individual identification, if they meet the criteria described in the guidance.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, September 07, 2017 4:40 AM
To: OC GCP Questions
Subject: Using subjects blood samples for further analysis after the study closure

Hello,

Kindly advice if in any case the sponsor can use the subjects back-up blood samples for further analysis after the study closure and CSR generation which is neither mentioned in earlier study protocol nor in informed consent.

If yes, kindly guide on the documentations that to be generated for this task. If the subjects are to be informed, kindly clarify if a separate consent would be required in [redacted] scenario where video consenting is mandatory, or a telephonic consent to the subject or LAR would suffice.

Kind regards

[redacted]